

DEPARTMENT OF HEALTH
WASHINGTON STATE BOARD OF PHARMACY
MEETING MINUTES

April 20 – 21, 2006

Red Lion Inn

Yakima Center

607 E. Yakima Ave.

Yakima WA 98901

CONVENE

Board Chair Asaad Awan called the meeting to order at 11:30 a.m. on April 20, 2006. Board Members present:

Donna Dockter, RPh
Gary Harris, RPh
George Roe, RPh
Rebecca Hille, Vice-Chair
Rosemarie Duffy
Susan Teil-Boyer, RPh

Staff Members present:

Joyce Roper, Assistant Attorney General
Steven Saxe, Executive Director
Lisa Salmi, Deputy Executive Director
Tim Fuller, Pharmacy Consultant
Andy Mecca, Pharmacy Consultant
Grace Cheung, Chief Investigator
Jim Doll, Pharmacist Investigator
Doreen Beebe, Program Manager

April 20, 2006

Open Meeting

CONSENT AGENDA

- 1.2 Pharmacy & Other Firm Application Approval
 - Closed & New Pharmaceutical Firms Report 2/13/2005 thru 04/07/2006
- 1.3 Pharmacy Technician Application Approval
 - Kentucky Tech-Central Campus in Lexington KY\Gladwyne Reed
 - Tehran University of Medical Services\Negar Golchin
 - Draughons Junior College in Clarksville TN\Teresa Lewis
- 1.4 Pharmacy Technician Training Program
 - Nebraska Medical Center/Justin Gripp
 - Valu Drug – Montesano WA
- 1.5 Collaborative Drug Therapy Agreement Acceptance
 - Nancy Hecox – Fred Meyer/Antibiotic Treatment
 - Prescriber Leslie Miller-Various/3-month Bridging Study
 - Steven Wanaka – Children's Hospital/Total Parenteral Nutrition
 - Tom Engel – Northwest Prescriptions & Medical Supply/Anticoagulation
- 1.8 Board Minute Approval

- March 10, 2006 meeting minutes

Items 1.1-Pharmacist License Application Approval; 1.6 – Automated Drug Dispensing Device Acceptance; and 1.7- Sample Distribution Requests were deleted from the consent agenda.

MOTION: Vice-Chair Rebecca Hille moved to accept the consent agenda items 1.2; 1.3; 1.4; 1.5; and 1.8 with the correction to the spelling of Ms. Hille's name on page 6 of the March meeting minutes. **MOTION CARRIED.**

REPORTS

Steve Saxe reported on the following:

- Optometry Board held its continuing education two day seminar with approximately 650 attendees.
- Work continues with the Governor's office for appointments to the Veterinary Board of Governors. A public member was recently appointed; however there are still several vacant positions.
- Mr. Saxe attended the American College Healthcare Executives as the state representative for Washington. The meeting focused on ethics, personal and professional growth, and networking. This is Mr. Saxe's last year of his elected 3-year term.
- Mr. Saxe and George Roe attended the National Association of Boards' of Pharmacy (NABP) annual meeting. The meeting provided an opportunity to network with other state boards and executive directors.
- Board Chair Asaad Awan and Vice Chair Rebecca Hille will be attending the Department of Health (DOH) Board & Commission Leadership Conference on April 26th.
- Chief Investigator Grace Cheung, Board Investigators Stan Jeppesen and Tim Fuller will be attending a forum hosted by the federal Drug Enforcement Agency (DEA) and the Oregon Board of Pharmacy later this month looking at the issue of drug disposal. The issue relates well with the Washington Board of Pharmacy's activities with drug disposal pilot projects and is specifically focused on the disposal of controlled substances, which is difficult complying with both ecology and drug rules. The meeting will be attended by representative from the states of Washington, Oregon, Wyoming, Idaho and Montana.
- DOH – Health Systems Quality Assurance is further developing organizational changes based on functionality similarities throughout the division. The Board requests that Laurie Jenkins, HSQA Assistant Secretary or Bonnie King, HPQA Director be invited to speak at a future meeting.
- Reporter Michael Behrens of the Seattle Times will be releasing a report based on a culmination of research reviewing the department's disciplinary process focusing primarily on sexual misconduct. The first of a four part series will be published April 22nd.

BOARD MEMBERS

Gary Harris – is involved in a project with Washington Association of Diabetes Educators and several pharmacy chains – Fred Meyer, Bartell Drugs and Rite Aid in developing diabetes curriculum for retail pharmacist. The project is in its initial planning stages, formation of a committee to develop the curriculum is expected to be completed in July, with classes held in September.

George Roe attended NABP Annual Meeting and was appointed a delegate to the Resolutions Committee. This Committee is tasked with reviewing and declaring which resolutions are passed, withdrawn or moved forward with no recommendations. Resolutions passed or moved forward go before the whole delegation for vote. Highlights included the former Secretary of U.S. Health & Human Services, Tommy Thompson who spoke on the issue of Medicare.

Mr. Roe also attended a class on communications which included discussed how to manage media interviews and getting your message out by using short headline type of statements. In addition, discussions included participation in the Katrina disaster and the problems encountered related to pharmacy practices; such as, the authority of out-of-state pharmacies to dispense, checking and maintaining the quality of drugs, control of drug abuse, patients not knowing the drugs they are prescribed, no electricity, and lack of access to tools pharmacists typically uses – stationary, etc.

Susan Teil-Boyer – referred to the American Pharmaceutical Association (APhA) conference where Bruce Canaday, the new president of APhA and former president of American Society of Health System Pharmacists (ASHP) gave an address about the future of the pharmacy profession and the use of technician, and technology. Ms. Teil-Boyer suggested that this discussion be considered for the Board’s strategic planning session.

Ms. Boyer shared with the Board that Good Samaritan Hospital participated in emergency management drill held by Pierce County. It was a valuable learning experience in identifying what went well and the deficiencies in the process in taking care of community needs during an emergency.

Donna Dockter - also attended the APHA conference.

CONSULTANT PHARMACISTS

Tim Fuller reported:

- On April 5th the state held its second emergency preparedness drill in Pierce County called the Tacoma Resilience. Board staff Tim Fuller, Lisa Salmi, Jim Doll, and Jackie Stockdale participated in the receiving and distributing antibiotics related to a biological agent emergency. The warehousing exercise went very well. Issues identified – locating delivery points, software problems and additional need for pharmacists in specific locations.
- Met with Department of Health Facility and Licensing Construction Review staff regarding questions on USP797 (Regulations for the Compounding of Sterile Preparations) requirements and the Board’s position.
- Presented background on controlled substances laws to the Bastyr College Naturopathy law class.
- Provided support to the Nursing Care Quality Assurance Commission on issues related to legislation for school nurses and access to asthma medications.
- Working on rules using the new electronic system for filing. Rules currently in progress include; the Automated Distribution Device rules, Pharmacist Responsibility, Pharmacy Technician, Long-term Care, etc. Mr. Fuller acknowledged support provided by Tami Thompson, DOH HPQA Policy Coordinator.

Andy Mecca indicated that he has received several questions from doctors' offices asking for interpretations on laws related to dispensing medications to their patients and methadone treatment. He advised them of the requirements for office dispensing such as labeling, recordkeeping, etc.

Mr. Mecca updated the Board on the interagency committee's working on establishing opioid dosing guidelines. The committee's next meeting is May 1st.

CHIEF INVESTIGATOR

Grace Cheung reported on the following:

- Presented with Andy Mecca to the Spokane area pharmacists on April 9th. The presentation was part of the New Laws, New Drugs continuing education program sponsored by the University of Washington (UW) and the Washington State Pharmacy Association (WSPA).
- On March 8th, Investigator Jim Lewis provided the Clark College Technician class with an overview of Pharmacy Law relevant to the role of the pharmacy technician.
- Investigators Joseph Honda and Dick Morrison gave a presentation to a group of Seattle-area researchers on March 15th. The goal of the presentation was to promote voluntary compliance of laws and rules by providing information regarding Pharmacy Board inspection process for researchers, controlled substance recordkeeping requirements, DOH/Board expectations, and answer questions.
- Ms. Cheung and several of the investigators will assist the instructors at the UW Pharm 440 communications lab classes in April and May. This activity provides the Board a unique opportunity to impress upon the students, many of whom are interns, the importance of patient counseling.
- On April 6, Investigator Dick Morrison gave a lecture on pharmacy law to Bartell Drug technicians-in training.
- On April 17th Investigator Bill Kristin provided an overview of pharmacy law to the Pharmacy Technician class at Spokane Community College.
- Rosemarie Duffy will attend the June Investigator's meeting in Tumwater.

PROGRAM MANAGER

Doreen Beebe reported on the following:

- Unofficial offer for a new support person has been submitted for approval. The person will be on board before the June Board meeting.
- New Board Orientation scheduled for May 31st.

PRESENTATIONS

Yakima Valley Farm Worker's Clinic

Tim Fuller provided an introduction to a presentation by the Yakima Valley Farm Worker's Clinic. YVFWC has requested approval to establish a Call Center off-site from the pharmacy and staffed by trained agents not credentialed by the Board.

Presenters: Patrick Bucknum, Director of Operations; Brandy White, Pharmacy Manager – Yakima; Dan Scott, Pharmacy Manager – Grandview; and Leon Wilde, Pharmacist Consultant

Key Points

- Provides services to the un-served or underserved patients.
- YVFWC is an approved 340B drug pricing program.
- YVFWC is (JCAHO) Joint Commission of Accreditation for Healthcare Organizations accredited since 2000.
- IVA system creates unique challenges for YVFWC's patients such as language barriers.
- YVFWC's pharmacies currently receive per pharmacy approximately 100 refill calls in an 8 hour business day.
- Operates 5 pharmacies – Yakima, Toppenish, Grandview, Walla Walla and Spokane.
- Call Center Functions
 - Similar to IVA system – but staffed by live call-center agent.
 - Verify refills are available through pharmacy system by refill number.
 - Ability to queue refill request at the appropriate pharmacy.
 - Ability to connect patient to pharmacy/provider
 - Answer non-pharmacy related inquiries – location, time of operation, etc.
 - Access to patient's records – HIPAA and confidentiality training – Patients registered in the YVFWC system signs agreement to allow access to records by YVFWC staff.

Key Issues/Concerns

- Non-credentialed staff with access to pharmacy/clinic system
 - No Board oversight of call-center agents
 - Misfills
 - Dosing Issues
 - Limit access to refill information not complete patient records
- Off-site from pharmacy without a pharmacist's direct supervision
- Diversion
- Policies and Procedures – Quality Assurance

MOTION: Donna Dockter moved to approve the proposal by the Yakima Valley Farm Work's Clinic Pharmacy Call-Center provided that the Call Center is located in the same building as a licensed YVFWC's pharmacy and the Call Center has implement written policies and procedures to monitor calls for quality assurance. All Call Center staff must be registered as pharmacy assistants and shall receive appropriate training. YVFWC will provide an update to the Board on the progress of the Call Center in six months after implementation. **MOTION CARRIED** with 6 supporting the motion and 1 opposed (George Roe). **AMENDED MOTION:** Chair Asaad Awan moved that the motion is amended to restrict the approval to 340B approved programs. **MOTION CARRIED.**

DISCUSSION

Rules Update

A spreadsheet of current rules in process was distributed to the Board. Steve Saxe updated the Board on their status.

- Automated Drug Distributing Devices – lead Tim Fuller – CR 102 package submitted and up for hearing July 2006.
- Suspicious Transactions – CR102 submitted and waiting comments for the department's economist on the Significant Bill Analysis and Significant Small Business Economic Impact Statement.

- Long-Term Care Facilities Destruction of Controlled Substances
- Adding Soma to CSA – proposed by UW students this proposal has been withdrawn at this time and projected for re-filing.
- Wholesaler Rules - working on CR101 package.
- Sexual Misconduct Rules – CR101 package filed. Stakeholder meeting set for July in tandem with the Veterinary Board of Governors. Plans are being finalized for the July stakeholder meeting to be held in Tumwater and via teleconference in Spokane.
- Pharmacist Responsibilities - stakeholder meeting held April 19 and 20.
- Technician National Examination – stakeholder meeting April 20.

2007 Legislative Input

Steve Saxe updated the Board on 2007 suggested legislation for agency consideration. He also asked the Board if they had any concerns or additional suggests.

- Wholesaler Rules
- Prescription Monitoring
- Methamphetamine Legislation – State Law comparison to Federal Regulations

MOTION: Vice-Chair Rebecca Hille moved that the Board support the suggested 2007 legislation for wholesaler rules, prescription monitoring and methamphetamine proposals for agency approval. **MOTION CARRIED.**

GMAP – Government Management Accountability and Performance

Grace Cheung provided the Board with an overview of the pharmacy inspection and investigations' GMAP report. She shared with the Board the difficulty they are having in pulling out the data necessary in creating the GMAP report from our current computer systems. The report itself was not distributed due to problems with the data. Instead, Ms. Cheung provided an overview of the information the report is designed to capture and the duties not reflected in the report. Investigators have five main duties investigations, inspections, education, consultant and practice reviews. Practice reviews may or may not be linked to discipline orders. GMAP will report investigations and inspections only.

- Inspections include canine handlers, researchers, pharmacies, etc.
- Each Investigator has an average of 300 locations.
- The goal is to inspect each location every 24 months (locations over 24 month goal are considered pending).
- Monthly Data reported identifies the number of pending locations compared to inspections completed.
- Inspections include: routine, new, relocations, re-inspection (location previously failed). System does not account for the different types of inspections and therefore the data is flawed.

The investigators' are currently keeping manual logs to record time spent doing activities that will need to be documented in the GMAP report. Pharmacist Investigator Jim Doll has been assisting in the task of attaining meaningful data. Ms. Cheung hopes to develop a baseline by which to plan and set performance goals. She wants to illustrate the dissimilarities in inspection workloads of various pharmacy practices that may not be reflected solely in the total number completed.

Steve Saxe added that our current databases capture the data, but do not provide a method for tracking and/or monitoring investigators' daily activities. In addition, these systems are not

supported by our Information Technology staff. We may be looking at purchasing an off-the-shelf system that can interface with the ILRS system (new licensing system) and is supported by our IT staff. The proposal for a pharmacy inspection system will move forward as a budget request for the next fiscal year.

Operating Agreement

The Board reviewed the proposed operating agreement and addendum with the Department of Health regarding administrative matters. The Board requested to take a look at the last agreement signed on June 7, 1990. Concerns include budget development and personnel issues.

The Board questioned whether or not the Secretary would be willing to consider modifications to the agreement template. Note: the addendum addresses the program's unique circumstances that have a statutory basis.

Joyce Roper expressed a possible conflict of interest in advising the Board in this matter.

The Board is postponing a decision on this agenda item and requests additional information and legal counsel. It was suggested that the Board extend an invitation to a future meeting to a former Board member for historical background.

Correspondence

The Board reviewed and discussed correspondence addressed to the Board from NABP regarding:

- Requests for volunteers to serve on the Associations' committees and task forces in 2006-2007.
- Foreign Pharmacy Graduate Equivalency Examinations administered in New York, Chicago and San Francisco in June 2006.
- Revisions to the Foreign Pharmacy Graduate Examination Committee policy for eligibility for FPGEC Certification.
- Additional proposed resolutions for consideration at NABP's 102nd Annual Meeting.
- To improve processing times for FPGEC Certification, NABP has partnered with Educational Credential Evaluators. As a result, the fee for evaluation of applications has increased.
- Results of a national survey of prescription drug repository program (donation of unused prescriptions). This issue did come up during the 2006 legislation.
- Report of the 2005-2006 Task Force on Model Regulation for Long Term Care – for institutional pharmacies.
- Standards 2007 – new standards and guidelines for the Doctor of Pharmacy Degree, effective July 1, 2007.
- Report of 2005-2006 Task Force on Standards for Compounding.
- Pharmacist reports a request for pharmacy's NABP ID number.

Board members were asked to review correspondence and request staff to add items to future board agendas.

Notice of Corrections (NOC) & Stipulation to Information Disposition (STID)

Kristy Weeks, staff attorney provided a brief overview on Statement of Allegations, Stipulation to Informal Disposition and Notices of Corrections.

Notice of Correction – is not issued under the Uniformed Disciplinary Act. It is issued under another section of the RCW’s that authorizes their use when in the course of an inspection or investigation the investigator finds a clear violation of a technical rule or law. Because they are not under the UDA we can not issue sanctions. It does become part of their professional record and is available by public disclosure request. NOC’s are not reported to the National Practitioner Date Bank and is not included on the DOH website provider credential look-up. A statement of appropriate corrective action should be provided during the investigation and before a decision to issue a NOC.

Notice of Correction

Can NOT be issued for:	Can be issued for:
<ul style="list-style-type: none"> ▪ standard of care issue ▪ unclear violation of technical rule- it either is or it isn’t ▪ violation is denied (no right to appeal) 	<ul style="list-style-type: none"> ▪ Often used for a misfill where a pharmacist has taken corrective action ▪ Clear violation of technical rule e.g. ancillary staff failing to wear name badges

Statement of Allegations – This document states the allegation and the evidence. This is not formal discipline and is accompanied by an STID (see below).
 Stipulations to Informal Disposition (STID) –This document reiterates the allegation, states that no finding has been entered and no admission required; however conditions are imposed. STID’s are reported to the National Practitioner Databank and included on the DOH credential look-up. A STID may be issued anytime prior to issuing a Statement of Charges. A STID has the same evidentiary standards as an SOC. A STID is generally not open to negotiation.

Stipulations to Informal Disposition

What sanctions can <u>not</u> be imposed: <ul style="list-style-type: none"> ▪ Suspend ▪ Revoke ▪ Fine ▪ Censure or reprimand May not be appropriate when: <ul style="list-style-type: none"> ▪ Anticipate compliance issue ▪ Denying responsibility Disadvantage <ul style="list-style-type: none"> ▪ Non-compliance with conditions can not be fast tracked. 	What sanctions can be imposed: <ul style="list-style-type: none"> ▪ Cost recovery up to \$1000 per allegation ▪ Probation May be appropriate when: <ul style="list-style-type: none"> ▪ First Offense ▪ Lesser offense ▪ Respondent has taken responsibility Advantage <ul style="list-style-type: none"> ▪ Quicker and cheaper
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Open Forum

No comments provided.

Meeting adjourned at 5:00 pm.

Chair Asaad Awan called the meeting to order at approximately 9:00 am. All board members and staff from the previous day were present. The Board assembled to review comments from stakeholder workshops held on April 19 and 20 and to discuss the next steps.

Wendy Fraser, the facilitator contracted to assist the Board in this process, acknowledged that last night the Board received copies of letters, and notes and comments from both stakeholder workshops related to a pharmacist's responsibilities. In addition, all 4800 letters, emails and written telephone messages received were available for the further Board's inspection.

Following Chair Asaad Awan and Vice-Chair Rebecca Hille summary of the events and public comments received on April 19th, the Chair called for an executive session to consult with counsel regarding possible litigation.

The Board reconvened approximately 35 minutes later.

Ms. Fraser asked the Board to consider issues and concerns surrounding the matter of a pharmacist's responsibilities when presented with a lawful prescription. The Board's discussion centered on the four questions asked at the earlier stakeholder workshops.

1. What are a pharmacist's professional responsibilities when presented with a lawful prescription?
2. Under what circumstances may a pharmacist/pharmacy refuse to fill a prescription?
3. What expectations should patients have when seeking professional services from a pharmacy?
4. What would characterize unprofessional conduct by a pharmacist?

Unprofessional Conduct - identified by the Board (facilitator's poster paper notes)

- Giving wrong information
- Verbal or non-verbal harassment
- Doing something that is not in the best interest of the patient (e.g. destroying a legal prescription)
- Not obeying the law
- Fraud
- Changing the prescription without attempts to contact the provider
- Unauthorized altering of a prescription
- Practicing under the influence
- Not filling a prescription (e.g. long weekend)
- No attempt to ensure care

MOTION: Vice-Chair Rebecca Hille moved that the Board start the rule making process to further define unprofessional conduct. **MOTION CARRIED.**

The Board provided staff with direction to develop a rough draft and requested that the draft be rewritten in rule language and brought before the Board on May 2nd for further discussion.

Meeting adjourned 12:10 p.m.

CLOSED SESSION – Case Presentation

Adjournment

There being no further business, the Board adjourned at 2:00 p.m. They will meet again on May 2, 2006 in Kent Washington for a special meeting and on June 1 & 2, 2006 in Tumwater, Washington for its regularly scheduled meeting.

Respectfully Submitted by:

Doreen E. Beebe, Program Manager

Approved on June 1, 2006

*Dr. Asaad Awan, Chair
Board of Pharmacy*